K020899

DEC 13 2002

Pneupac

Summary of Safety and Effectiveness

Submitter:	**Pneupac Ltd.**
Address:	**Bramingham Business Park, Enterprise Way, Luton, Bedfordshire, LU2 OAH United Kingdom.**
Telephone:	**(+44) (0) 1582 430000**
Contact:	**Regulatory Affairs & Quality Assurance Manager**
Prepared:	**29th June 2001**
Proprietary Name:	**paraPAC 'Medic' models 200 & 200D**
Common/ Classification Name:	**Gas powered Emergency Ventilator with Electronic alarms**
Predicate Devices:	**paraPAC 'Medic' Gas Powered Emergency Ventilator (K960515)**

New Device Description:

The paraPAC 'Medic' ventilator is a gas powered, time cycled, volume preset, pressure limited ventilator which uses the same technology as existing legally marketed devices. It depends solely on the pressure of the supply gas for its operation. Additionally, it incorporates an integrated electronic pressure alarm unit to alert the user to certain significant changes that may occur in the patient's ventilation. Loss of battery power for the alarm is signalled to the user but will have no effect on the ventilation performance of the paraPAC 'Medic' ventilator, nor affect the mechanically operated alarms and protection systems, which operate in an identical manner to the predicate device, except for the addition of a mechanically operated gas supply indicator and the addition of a secondary relief valve.

The paraPAC 'Medic' ventilator consists of a control module and patient circuit comprising the

Pneupac Limited.
Bramingham Business Park,
Enterprise Way, Luton, Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac@smiths-industries.com
www.pneupac.co.uk

Pneupac

Summary of Safety and Effectiveness

New Device Description (ctd.):

following disposable items: Hose/ Patient Valve/ PEEP Valve/ Exhaust Collector and Mouthpiece. The module is available as either a non- demand version (P200) or demand version (P200D), and weighs 2.7 kilograms (non-demand version) or 3.1 kilograms (demand version) respectively.
The module control panel for both models have the following features:

- Adjustable Relief Pressure Control, range 20 to 80 cm H_2O.
- Air Mix (45% oxygen) / No Air Mix (100% oxygen) Selector.
- Tidal Volume Control, range 65 to 1570 ml.
- Frequency Control, range 8 to 40 b.p.m. with click stop detent at 12 b.p.m. for Cardiopulmonary Resuscitation.
- Patient Inflation Pressure Manometer, range –10 to +100 cm H_2O.
- Supply Gas Failure Alarm – A mechanically operated visual alarm gives a warning that the supply gas has dropped to a pressure at which the ventilator will no longer be operating to specification (< 35 psi). With low pressure it shows red, with adequate pressure it shows white. Any visible red indicates that the supply should be changed. In most cases the display will begin to oscillate from white to partial red as the supply pressure falls to the lower threshold level.
  The visual indication will be accompanied by an electronically generated medium priority* audible warning. In order to conserve the battery, if this audible alarm is ignored for more than 60 seconds the alarm system will ultimately switch itself off.
- Electronic alarm bezel indicating:
  - High Pressure Indicator – Flashes Red LED with audible alarm at set relief pressure and with continuous positive pressure.
  - Normal Cycle Indicator – Flashes Green LED every time inflation pressure rises through 10 cm H_2O.
  - Low Pressure/ Disconnect Indicator – Flashes Yellow LED with audible alarm if pressure does not rise through 10 cm H_2O within ten seconds.
  - Silence button – silences audible alarm for 60 seconds. Flashes Orange LED to indicate to the operator that the audible alarm is silenced.
  - Breathing detect indicator (demand model only) – Flashes Green LED each time a spontaneous breath is detected.
  - Low battery indicator - Flashes Yellow LED with audible alarm.

Pneupac Limited.
Bramingham Business Park,
Enterprise Way, Luton, Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac@smiths-industries.com
www.pneupac.co.uk

Pneupac

Summary of Safety and Effectiveness

Intended Use:

The paraPAC 200 & 200D 'Medic' ventilators are portable, gas powered, time cycled ventilators which depend solely on the pressure of the supply gas for their operation. These models additionally incorporate an integrated electronic pressure alarm unit to alert the user to certain significant changes that may occur in the patient's ventilation. Loss of battery power for the alarm is signalled to the user but will have no effect on the ventilation performance of the paraPAC 'Medic' ventilator, nor affect the mechanically operated alarms and protection systems that exist on the predicate device already on the market.
They are specifically designed for use by paramedic and other qualified persons, for adult, child and infant (above approx. 5 kg) ventilation during cardiopulmonary (CPR), as well as for rescue breathing, in accordance with the 1986 'JAMA' standards.
The paraPAC 'Medic' ventilators and accessory equipment conform to European Standard EN 794-3 "Particular Requirements for Emergency and Transport Ventilators" and comply with the requirements of the European Directive for Medical Devices 93/42/EEC.
The 200D model is suitable for the treatment of victims in rescues from toxic or non respirable atmospheres as it offers the choice of 100% oxygen upon demand or ventilatory back-up to the patient whilst normal breathing is being restored.
This Controlled Mandatory Ventilation/ Demand feature may also be used for weaning patients back to normal breathing from controlled ventilation.

Performance Data:

The design of this ventilator uses currently available technology found in many legally marketed ventilators. Testing was performed to ensure that the paraPAC 'medic' models 200 & 200D were safe and would perform within the environment(s) for which they are to be marketed.

Safety testing was conducted in accordance with the Draft Reviewer's Guidance for Ventilators, July 1995, EN794-3 'Lung Ventilators – Part 3 Particular requirements for emergency and transport ventilators" 1999 and EN60601-1 'Medical Electrical Equipment – Part 1 General requirements for safety': 1990. The ventilator passes all of these tests and met all requirements of the standards

Environmental testing was performed in accordance with EN 60601-1-2: 1993 and EN794-3: 1999.

Pneupac Limited.
Bramingham Business Park.
Enterprise Way. Luton. Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac @ smiths-industries.com
www.pneupac.co.uk

Pneupac

Summary of Safety and Effectiveness

Performance Data (ctd.):

Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/ humidity testing has been completed. The results demonstrated that the paraPAC 'medic' models 200 & 200D complied with the guidelines and standards and that they performed within their specifications and functional requirements.

Comparison testing of the paraPAC 'medic' models 200 & 200D with their respective predicate counterparts the paraPAC 'medic' 2 and 2D (non demand and demand versions respectively) was done to show that the performance of the delivered Tidal Volume, Frequency, Inspiration times and Expiration time parameters are the same for each. The tests were performed across the ventilator's entire range. All measurements were within the specified tolerances of the ventilators. These data support substantial equivalence of the paraPAC 'medic' model 200 to the paraPAC 'medic' model 2 and the paraPAC 'medic' model 200D to the paraPAC 'medic' model 2D.

The testing described above indicates that there is no functional difference between the operation of the paraPAC 'medic' models 200 & 200D with their respective predicate counterparts the paraPAC 'medic' 2 and 2D for delivered Tidal Volume, Frequency, Inspiration times and Expiration time parameters. Based on these results, it is our determination that the device models are safe, effective and perform as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,

Colin Walters

Colin Walters
Regulatory Affairs and Quality Assurance Manager

Pneupac Limited.
Bramingham Business Park.
Enterprise Way. Luton. Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac @ smiths-industries.com
www.pneupac.co.uk

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

Pneupac Limited
C/O Mr. Donald Alexander
Vice President of Regulatory Affairs
BCI Incorporated
N7 W22025 Johnson Road
Waukesha, Wisconsin 53186-1856

Re: K020899
Trade/Device Name: paraPAC 200 Medic and paraPAC 200D Medic
Regulation Number: 21 CFR 868.5925
Regulation Name: Emergency Powered Ventilator (Resuscitator)
Regulatory Class: II
Product Code: BTL
Dated: September 13, 2002
Received: September 16, 2002

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

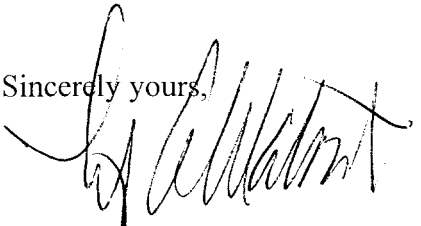
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) SUBMISSION: K020899

ATTACHMENT # 11

Indications For Use

510(k) Number (if Known): K020899

Device Name: paraPAC 200 'Medic' Emergency gas powered Ventilator

Indications For Use:

Intended Use:

The paraPAC 200 & 200D are portable, gas powered, time-cycled ventilators that are designed for emergency ventilation of patients who have respiratory distress or insufficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K020899